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## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

FEB 2 4 1995

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

Subject: ETU (Ethylene Thiourea) Revised  $Q_1^{\bullet}$ , (3/4's Interspecies Scaling Factor), NTP  $B_6C_3F_1$  Mouse Dietary Study

Caswell No.443AA

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The revised unit risk,  $Q_1^*(mg/kg/day)^{-1}$  of ETU, based upon female ( $F_1$ ) mouse liver (adenoma and/or carcinoma) tumor rates is  $6.01 \times 10^{-2}$  in human equivalents (converted from animals to humans by use of the 3/4's scaling factor-1994, Tox\_Risk, 3.5-K.Crump)\*. The dose levels used in the mouse study were 0, 100, and 330 ppm of ETU. The corresponding tumor rates in female mice were 9/98, 4/27 and 136/150. These doses and rates were obtained from the memorandum "Ethylene Thiourea (ETU) -  $Q_1^*$  Calculation Based on Female Mouse Liver Tumors (Pooled Data) from NTP Study, H.Pettigrew, 11/13/91)."

See Memo - Deriving Q<sub>i</sub>'s Using the Unified Interspecies Scaling Factor, P.A. Fenner-Crisp, Director-HED, 7/1/94.

cc: Caswell file

B.Doyle

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## Dose-Response Analysis

Since the female mice did not have significant differential mortality with incremental doses of ETU, the estimate of unit risk,  $Q_1$ , was obtained by the application of the Multi-Stage model (Tox\_Risk program, version 3.5 - K.Crump).

The estimate of unit risk,  $Q_1$ , was based upon liver (adenoma and/or carcinoma) tumor rates observed in female mice.

The resulting estimate of unit risk, Q1°, is as follows:

Species, Strain, Sex

Tumor

Q<sub>1</sub>\* (mg/kg/day)<sup>-1</sup>
in Human Equivalents\*

Mouse, B<sub>6</sub>C<sub>3</sub>F<sub>1</sub>, Female

Liver (Ad &/or Ca)

6.01x10<sup>-2</sup>

For the conversion to human equivalents, weights of .0343 kg for the mouse, 70 kg for humans and the 3/4's scaling factor were used. Food consumption was 5.7 g/day as presented in the study.

It is to be noted that  $Q_1^{\bullet}$  (mg/kg/day) is an estimate of the <u>upper bound</u> on risk and that (as stated in the EPA Risk Assessment Guidelines) "the true value of the risk is unknown, and may be as low as zero."